EXHIBIT S

From: Lias, Courtney H <Courtney.Lias@fda.hhs.gov>
Sent: Wednesday, October 1, 2014 8:37 AM
To: Pilcher, Ian
Cc: Serrano, Katherine M; Kelm, Kellie; Chan, Yung; Elder, Ileana
Subject: RE: Theranos Inspection Assignment
Attachments: Theranos Inspection Request CL.doc.bin

Hi Ian ?

I do have some comments for clarification. Happy to discuss if you want.

Thanks,

Courtney

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
Food and Drug Administration
Ph 301-796-5458

From: Pilcher, Ian
Sent: Tuesday, September 30, 2014 4:13 PM
To: Lias, Courtney H
Cc: Serrano, Katherine M; Kelm, Kellie; Chan, Yung; Elder, Ileana
Subject: Theranos Inspection Assignment

Courtney,

Attached is the draft Theranos inspection assignement, please let me know if you have any questions, comments, or suggestions.

Thanks,

Ian

Ian Pilcher
Regulatory Scientist
Division of Chemistry and Toxicology Devices
FDA/CDRH/OIR
301-796-6151

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

DATE: [ENTER DATE ASSIGNMENT IS ISSUED]

FROM: Division of Chemistry and Toxicology Devices, WO-5615
Office of In Vitro Diagnostics and Radiological Health, CDRH

SUBJECT: **Directed Inspection Request**
OC Control Number:_____ (*FISB enters for domestic assignments*)
FACTS ID Number: _____ (*FISB enters*)
ORA Concurrence Number: _____(FISB *enters*)

TO: District Director: SAN-DO, HFR-PA100

FIRM: Theranos, Inc.
Address #1 (from Registration and Listing Database)
7333 Gateway Blvd.
Newark, CA 94560
FEI/Registration Number: 3006231732
Site Activity: Specification Developer and Manufacturer
Status: Active
Date of Registration Status: 2014
Owner/Operator Number: 10041002

Address #2 (from Registration and Listing Database)
1601 S. California Ave.
Palo Alto, CA 94304
FEI/Registration Number: 3010479366
Site Activity: Manufacturer
Status: Active
Date of Registration Status: 2014
Owner/Operator Number: 10041002

Official Correspondent:
Brad Arlington
1601 S. California Ave.
Palo Alto, CA 94304
Phone: 650-856-7304

DEVICE: Capillary Tubes and Nanotainers

Product Codes:
75-JKA,-Tubes, Vials, Systems, Serum Separators, Blood Collection
Class II, 21 CFR 862.1675;

81-GIO: Tube, Collection, Capillary Blood
Class I, 21 CFR 864.6150

75-JJE: Analyzer, Chemistry (Photometric, Discrete), for Clinical Use
Class I, 21 CFR 862.2160

High Priority, Domestic - this assignment has the concurrence of ORA.

[Completion within 60 days - Assignment takes precedence over other device work]

PRE-INSPECTION TELECONFERENCE:

This assignment is of significant nature and/or sufficient complexity that CDRH requests a pre-inspectional teleconference take place between CDRH, ORA, and the Investigator prior to initiating this inspection. OMPTO will coordinate the teleconference. CDRH will brief the investigator/s, clarify assignment expectations, answer any questions about the assignment, and make arrangements with the investigator for any desired communications during the inspection, as applicable. DMPTI will notify FISB and ORA/OMPTO/MPTPOB of the name of the investigator and FISB will notify the assignment Originator.

I. OBJECTIVE(S) OF INSPECTION

To conduct a "For Cause" Directed Inspection of this firm in accordance with CPGM 7382.845 – Inspection of Medical Device Manufacturers in order to evaluate their compliance with:

Quality Systems (21 CFR Part 820)
Medical Device Reporting (21 CFR Part 803)
Corrections and Removals (21 CFR Part 806)
Medical Device Tracking Requirements (21 CFR Part 821)
Registration and Listing (21 CFR Part 807)

II. BACKGROUND

***Section 1*: Premarket pathway, Background, and Indication for use.**

Theranos Inc. is registered and listed as a manufacturer for specimen containers (procode KDT), called "Nanotainers", and capillary blood collection tubes (procode GIO) called "Capillary Tubes" and as a specification developer for clinical chemistry analyzers (procode JJE). The Nanotainers and Capillary Tubes are designed for use with analytical systems including the firm's "Theranos System". Theranos has designed and developed their Capillary Tubes and Nanotainers to collect, preserve, and transport the small sample volumes used for testing in their Theranos System. The Theranos System is composed of Theranos' sample processing units (TSPU) and Theranos' Laboratory Automation System (TLAS). The TSPU is a modular ~~unit~~ instrument that performs what the firm calls pre-analytic functions of the unit (i.e. sample preparation, reagent addition, signal generation, data pre-processing). These are the steps that are typically performed during sample preparation and analysis on clinical analyzers. The firm does not have 510(k) clearance or PMA approval for any of its products.

Theranos maintains in pre-submission number Q140057 that their Capillary Tubes and Nanotainers are class I 510(k) exempt devices because they are not intended to separate serum and non-serum components. However, the firm has also submitted documentation that describes some of their Nanotainers as containing anticoagulants with gel for centrifuging before they are shipped to the Theranos CLIA lab. These types of devices as well as Capillary Tubes and Nanotainers containing anticoagulants with or without serum separation gel are considered class II by FDA and require a 510(k). The firm has also stated that they are claiming k983517 as a predicate. This is a class II device requiring 510(k) clearance with product code JKA. The firm has stated that they intend to submit a 510(k) for the collection and transport devices.

Theranos is offering over 200 tests that include tests for cardiac markers, therapeutic drug monitoring, drugs of abuse, infectious diseases, cancer and tumor markers, thyroid markers, liver markers, immunology ~~tests~~markers, and others. These tests are used to diagnose and monitor diseases and to guide treatment decisions. Erroneous results could lead to the wrong diagnosis of diseases and incorrect treatment decisions that can cause serious irreversible injuries or death.

Theranos claims that they are currently performing all sample testing in their CLIA lab and therefore their devices are Laboratory Developed Tests (LDTs). However, in pre submission number Q140057, they stated that they are performing a number of immunochemistry assays (e.g., Vitamin D, TSH and fT4) on the Theranos System within their CLIA-certified laboratory. FDA ~~has previously regulated instruments manufactured by a firm for in vitro diagnostic (IVD) testing as medical devices and not as LDTs~~has had extensive discussions with Theranos about this activity and does not agree with the firm that the device used in their facility is an LDT; thus, the product would require premarket notification or premarket approval (depending on the test) and the facility is subject to quality system requirements~~. Since the firm believes that their TSPU device and reagents are LDTs and not medical devices, it is unclear if they are manufactured under the Quality System Regulations.~~ Theranos has stated that their future plan is to place their TSPUs in facilities (e.g., Walgreens pharmacies) around the

Commented [LCH1]: Though this is true, it also implies that we agree. I know we explain a little later that we don't, but let's rephrase this to be more clear that this is only how they have listed them.

Commented [LCH2]: The TPSU also does the analytical portion, though Theranos tries to downplay that. SO let's clarify that here.

Commented [LCH3]: Let's mention the assays they have on it since they are what would need clearance or approval.

Commented [LCH4]: Not only here but also in R&L

Commented [LCH5]: Did they say this? Because they also say that the tubes are to collect plasma.

Commented [LCH6]: Let's not use the term predicate. It implies a submission.

Commented [LCH7]: Add here that they have not and how long we have been talking to them about submitting.

Commented [LCH8]: Spell out

Commented [LCH9]: I don't think they have claimed the TPSU is an LDT. They listed it as a device.

country to perform testing. At this point it is unclear to FDA ~~where~~ whether the on-site ~~the~~ sample processing and testing is already taking place.

CDRH has informed Theranos that their Nanotainers and Capillary Tubes are class II devices and require 510(k) clearance. FDA has also informed Theranos that tests performed using their reagents on the TPSU require clearance or approval prior to being marketed~~.~~. H~~h~~owever the firm has not submitted 510(k)s or PMAs for these devices or given us a timeframe when they will submit despite multiple requests form the Center. ~~510(k)s~~.

Discussion with Theranos to date has led to the following concerns:

1. According to the Theranos website, the firm is offering over 200 tests using a sample size of only a few drops. The firm uses their own Nanotainer collection devices for this process. Pre-submission Q140057 describes these Nanotainers and states that they may contain the anticoagulants Lithium-Heparin (Li-Hep) or EDTA and serum separating gel. Theranos claims to be using these containers to collect samples and shipping them to a Theranos CLIA lab. As described above, FDA believes that these types of devices require 510(k) clearance, which Theranos has not obtained. FDA is concerned that these devices are adulterated under section 501(f)(1)(B) of the Act and misbranded under section 502(o) the Act because they are being distributed without 510(k) clearance.
2. In pre submission, number Q140057, Theranos discusses using 510(k) cleared clinical analyzers and reagents from other manufacturers in the Theranos CLIA lab. Theranos intends to use these clinical analyzers and reagents to test samples collected and transported to the CLIA labs using the Theranos Capillary Tubes and Nanotainers. The 510(k) cleared analyzers and reagents that Theranos intends to use are not currently 510(k) cleared for use with capillary blood or the small sample volumes collected and transported in the firm's Nanotainers. FDA is concerned that Theranos may not have performed adequate validation on their Nanotainer and Capillary Tube devices for use with reagents and analyzers cleared by other manufacturers for use with larger volume venous samples. The sample type and volume can have a significant impact on the performance of an assay: if they are not adequately validated, the Theranos sample collection devices could cause erroneous test results. These erroneous results could lead to incorrect diagnosis and treatment decisions.
3. FDA is concerned that Theranos may be distributing their TSPU system, which includes instruments and reagents that typically require 510(k) clearance or PMA approval. As described above, Theranos has been informed that FDA believes these types of devices require ~~510(k)~~ clearance or approval. If these devices are being used to report clinical patient results, then they may be adulterated under section 501(f)(1)(B) of the Act and misbranded under section 502(o) the Act because they are being distributed without 510(k) clearance

Section 2: **Inspectional History**

The inspectional history and current compliance status of the manufacturing facility involved in this assignment has been checked in FACTS.

FACTS has no record of a previous inspection for this firm.

Section 3: **Postmarket Signals**

Theranos has submitted multiple pre submissions to FDA. During the review of these submissions and subsequent discussions with the firm, FDA has become aware that the firm may be distributing their devices without ~~510(k)~~ clearance or approval. FDA has informed Theranos that they should submit 510(k)s or PMAs for their devices, but to date FDA has not received a ~~510(k)~~ submission for any of the Theranos devices. Recently, the firm has also issued several press releases stating that they are offering their clinical lab tests at multiple Walgreen's sites in at least two states. It is not clear from the press release or FDA's interaction with the firm whether testing is being performed at the Walgreen's sites or at the Theranos CLIA lab or which devices are being used to perform the testing.

The pre submission responses and press releases are attached (see below).

Section 4: **Reason for Inspection**

The Center is concerned that the firm is distributing devices without appropriate pre-market clearance or approval. In addition, CDRH is concerned that the firm may not have adequate design control procedures, complaint handling and investigation procedures, and MDR reporting procedures ~~because they claim to be an LDT provider, not a manufacturer subject to FDA regulations~~.

III. ASSIGNMENT

Please assess the following areas during the inspection of the Firm's facility:

1. Determine what devices the firm has distributed. Collect shipping records to document the names and types of devices that the firm has distributed. Specifically, determine if the firm has shipped any sample collection, processing or transport devices, clinical instruments, reagents, calibrators, or controls either to outside firms or to other Theranos locations. Collect a list of all customers that Theranos has distributed their devices to.

2. Obtain and evaluate design requirements for the Capillary Tubes,Nanotainers, TSUP, and TLAS to determine if design inputs are appropriate, unambiguous, and address the intended use of the device. Specifically, did design requirements specify use of the containers with the analytes and test systems that Theranos is currently using? Are design input requirements and design validation sufficiently documented for these devices? Do the different anticoagulants, sample types, and sample volume affect test

results?

3. Determine whether the firm has written plans to ensure that there is an adequate evaluation of conformance to design inputs, including acceptance criteria. Determine whether verification activities were planned and executed with the Capillary Tubes and Nanotainers used to collect capillary blood samples by intended users and tested for the analytes offered by Theranos with the reagents and instruments Theranos will use.

4. Determine whether the firm has written procedures for validating the device design, confirmed that these are documented for the Capillary Tubes and Nanotainers and that the devices conform to the performance stated in the labeling. For example, the firm should evaluate their device in the hands of the intended user (phlebotomists). ~~The validation tests should be completed using only the instructions provided in the device labeling.~~ In addition, the firm should have a risk analysis that adequately addresses design requirements including identification of potential risks associated with the use of the test strips with assays and reagents that will be used to test the samples.

Commented [LCH10]: Not necessarily. These are not yet waived, and they may be trained at this satge.

5. Determine whether the firm has written recall procedures for submitting written reports to FDA of any correction or removal actions required to be reported to FDA per 21 CFR 806. Determine whether recall procedures for the Capillary Tubes and Nanotainers include assessment of the reagents and instruments that will be used to test the samples collected with the Capillary Tubes and Nanotainers. Determine how the firm will determine recall reportability of the Capillary Tubes and Nanotainers when the samples they collect and transport are not the intended samples types for the reagents and analyzers used to test the samples.

Commented [LCH11]: Let's make sure they do this for the TPSU as well since they are using it and it is registered.

6. Determine whether the firm has written MDR procedures in accordance with 21 CFR 803.17 and whether the firm has established and maintains MDR event files in accordance with 21 CFR 803.18. Please obtain a copy of the firm's MDR procedures. Failure to have written MDR records should be listed on the FDA 483.

7. Determine whether the firm has adequate written procedures for receiving, reviewing, and evaluating complaints. Please obtain a copy of the firm's complaint handling procedures. Determine whether the procedure(s) addresses how to handle complaints for which it is unknown if the device problem is due to a Capillary Tube or a Nanotainer issue or due to an issue with the reagents or analyzers Theranos is using. Determine what criteria the firm uses to identify a Capillary Tube or Nanotainer issue versus a reagent or analyzer issue.

8. If the review of the firm's complaint files identifies complaints that were not reported under MDRs but appear to be reportable, please collect a copy of the complaint record(s). If the complaints include unreported malfunctions that would likely cause or contribute to a death or serious injury, include an explanation of the malfunction and its effect on the patient in the EIR. Obtain the firm's rationale for considering the event to be not reportable. If a large number of complaints are identified, obtain a copy of the

complaint record for a representative sample of the unreported complaints for MDR reportability review.

9. Determine whether the firm has adequate written procedures for identification, documentation, evaluation, segregation, and disposition of nonconforming product. Review the firm's nonconforming product files to determine whether it includes assessment of the Capillary Tubes and Nanotainers with the reagents and instruments being used or the Capillary Tubes and Nanotainers only. Determine what criteria and decision making process are followed to make decisions on nonconforming product investigations for issues involving the Capillary Tubes and Nanotainers.
10. If the firm is found to be manufacturing and distributing their own reagents, calibrators, or controls, evaluate and collect lot release criteria to determine if the performance of the lots released is equivalent to devices currently in clinical use.
11. Determine whether Theranos is using contract manufacturers to produce their medical devices. If they are using contract manufacturers, then review and collect the agreements in place with these manufacturers to determine specific roles and responsibilities of each firm in the manufacturing process.
12. Review and collect product labeling for all Theranos products.

13. The degree and depth of the inspection should not be restricted to the points noted above. Please use good judgment and critical thinking to determine scope of additional coverage.

Commented [LCH12]: Same comment. I don't want to imply that we only want them to check these thing for the tubes. We also want an inspection of what they are doing for their instruments.

Commented [LCH13]: I don't understand this one. None are legally marketed, so what do we want them to look at? Wouldn't there be an issue if they were distributing them at all? (including if they are distributing them to a separate site (e.g., their own lab)

IV. REGULATORY STRATEGY

If a violative situation is found at the firm, the district should consider issuing a Warning Letter or recommending appropriate regulatory action in accordance with Compliance Program 7382.845, Part V. Please send all EIRs with exhibits, the form FDA 483, firm response(s), to the indicated CDRH contact via the Compliance Management System (CMS).

V. REPORTING REQUIREMENTS

This assignment has the concurrence of ORA. ORA concurrence number is [Enter ORA concurrence number]

Product Codes: 81-GIO: Tube, Collection, Capillary Blood
75-JKA: Tubes, Vials, Systems, Serum Separators, Blood Collection
75-JJE: Analyzer, Chemistry (Photometric, Discrete), for Clinical Use

PAC(s): 82845G: medical device "for cause" inspection. Accomplishment hours: 85.9 hours.
81011: enforcement of MDR. Accomplishment hours: covered under GMP hrs.
82845B: Level II (Comprehensive) Inspection. Accomplishment hours: See FY2014 workplan.
81845R: Assessment of Firm's Correction and Removals Practices. Accomplishment hours: See FY2014 workplan.

82012: Registration and Listing. Accomplishment hours: See FY2014 workplan.

Recommended Inspection Completion Date: 90 days from issuance of the assignment

VI. CONTACTS

Scientific/technical questions concerning this assignment should be directed to:

Primary: Ian Pilcher, OIR/DCTD, 301-796-6151 (p), 301-796-8514 (f), Ian.pilcher@fda.hhs.gov

Alternate: Ileana Elder, OIR/DCTD, 301-796-6143 (p), 301-796-8514 (f), ileana.elder@fda.hhs.gov

MDR reportability questions should be directed to:

MDR Policy Branch, OSB/DPS
301-796-6670, MDRPolicy@fda.hhs.gov

ORA/ DMPTI Inspectional Contact:

Dolores Harper, 301-796-5439, Dolores.Harper@fda.hhs.gov

Upon completion of the assignment, copies of all reports, exhibits, documentary samples, follow-up assignments and the regulatory/administrative recommendations, if appropriate, should be forwarded to:

Branch Chief/ Field Inspections Support Branch
CDRH/OC/DAPO/FISB
WO66, room 2622
10903 New Hampshire, Ave.
Silver Spring, MD 20993-0002

Signature

Ian Pilcher

VII. ATTACHMENTS

The following documents are provided as attachments:

1. Pre Submission Q131644

2. Pre Submission Q131644 Response Memo
3. Pre Submission Q140057
4. Pre Submission Q140057 Response Meeting Minutes
5. Theranos press releases
6. Theranos website

Drafted: Ian Pilcher 9/9/2014
Reviewed: Ileana Elder 09/12/2014
Revised: Ian Pilcher 9/25/2014
Reviewed:
Reviewed:
Final:

Cc:

Elem4214	(HFC-1) ORA/OO Special Assistant	Wanda Honeyblue
WO66-2622	OC/DAPO/FISB	Thomas Slater, Branch Chief
WO66-2624	OC/DAPO/FISB	Fleadia Farrah (foreign)
HFR-PA150	DIB, SAN District	Darlene Almogela
Elem2130	ORA/OO/OMPTO/DMPTPO/MPTPOB	Dolores Harper
HFR-SW100	Device Field Committee Chair	Reynaldo Rodriguez
HFR-CE250	Device Field Committee Exec Sec	Lori Lawless
HFR-PA1	RFDD, PAR Region	Mark Roh
WO66-5688	OIR/PSPQ	Deputy Director James Woods
WO66-5640	DCTD	Division Director, Courtney H. Lias
WO66-5615	DCTD	Ian Pilcher

CTS Record:

Document Comments
Total Comments: 13

Author: Lias, Courtney H
Date: 10/1/2014 8:49:00 AM
Initial: LCH
Range: Though this is true, it also implies that we agree. I know we explain a little later that we don't, but let's rephrase this to be more clear that this is only how they have listed them.
Scope: Theranos Inc. is registered and listed as a manufacturer for specimen containers (procode KDT), called "Nanotainers", and capillary blood collection tubes (procode GIO) called "Capillary Tubes" and as a specification developer for clinical chemistry analyzers (procode JJE).

Author: Lias, Courtney H
Date: 10/1/2014 8:50:00 AM
Initial: LCH
Range: The TPSU also does the analytical portion, though Theranos tries to downplay that. SO let's clarify that here.
Scope: The TSPU is a modular unit instrument that performs what the firm calls pre-analytic functions of the unit (i.e. sample preparation, reagent addition, signal generation, data pre-processing). These are the steps that are typically performed during sample preparation and analysis on clinical analyzers

Author: Lias, Courtney H
Date: 10/1/2014 8:51:00 AM
Initial: LCH
Range: Let's mention the assays they have on it since they are what would need clearance or approval.
Scope: The

Author: Lias, Courtney H
Date: 10/1/2014 8:51:00 AM
Initial: LCH
Range: Not only here but also in R&L
Scope: maintains in pre-submission number Q140057

Author: Lias, Courtney H
Date: 10/1/2014 8:52:00 AM
Initial: LCH
Range: Did they say this? Because they also say that the tubes are to collect plasma.
Scope: because they are not intended to separate serum and non-serum components

Author: Lias, Courtney H
Date: 10/1/2014 8:52:00 AM
Initial: LCH
Range: Let's not use the term predicate. It implies a submission.
Scope: they are claiming k983517 as a predicate

Author: Lias, Courtney H

Date: 10/1/2014 8:53:00 AM
Initial: LCH
Range: Add here that they have not and how long we have been talking to them about submitting.
Scope: devices

Author: Lias, Courtney H
Date: 10/1/2014 9:51:00 AM
Initial: LCH
Range: Spell out
Scope: TSH and fT4

Author: Lias, Courtney H
Date: 10/1/2014 9:52:00 AM
Initial: LCH
Range: I don't think they have claimed the TPSU is an LDT. They listed it as a device.
Scope: . Since the firm believes that their TSPU device

Author: Lias, Courtney H
Date: 10/1/2014 11:32:00 AM
Initial: LCH
Range: Not necessarily. These are not yet waived, and they may be trained at this satge.
Scope:). The validation tests should be completed using only the instructions provided in the device labeling.

Author: Lias, Courtney H
Date: 10/1/2014 11:33:00 AM
Initial: LCH
Range: Let's make sure they do this for the TPSU as well since they are using it and it is registered.
Scope: Determine whether recall procedures for the Capillary Tubes and Nanotainers include assessment of the reagents and instruments that will be used to test the samples collected with the Capillary Tubes and Nanotainers. Determine how the firm will determine recall reportability of the Capillary Tubes and Nanotainers when the samples they collect and transport are not the intended samples types for the reagents and analyzers used to test the samples.

Author: Lias, Courtney H
Date: 10/1/2014 11:34:00 AM
Initial: LCH
Range: Same comment. I don't want to imply that we only want them to check these thing for the tubes. We also want an inspection of what they are doing for their instruments.
Scope: Review the firm's nonconforming product files to determine whether it includes assessment of the Capillary Tubes and Nanotainers with the reagents and instruments being used or the Capillary Tubes and Nanotainers only. Determine what criteria and decision making process are followed to make decisions on nonconforming product investigations for issues involving the Capillary Tubes and Nanotainers

Author: Lias, Courtney H

Date: 10/1/2014 11:36:00 AM
Initial: LCH
Range: I don't understand this one. None are legally marketed, so what do we want them to look at? Wouldn't there be an issue if they were distributing them at all? (including if they are distributing them to a separate site (e.g., their own lab)
Scope: criteria to determine if the performance of the lots released is equivalent to devices currently in clinical use.

Document Revisions
Total Revisions: 36

Author: Lias, Courtney H
Date: 10/1/2014 8:49:00 AM
Type: Delete
Range:

Author: Lias, Courtney H
Date: 10/1/2014 8:50:00 AM
Type: Delete
Range: unit

Author: Lias, Courtney H
Date: 10/1/2014 8:50:00 AM
Type: Insert
Range: instrument

Author: Lias, Courtney H
Date: 10/1/2014 9:50:00 AM
Type: Insert
Range: tests for

Author: Lias, Courtney H
Date: 10/1/2014 9:51:00 AM
Type: Delete
Range: tests

Author: Lias, Courtney H
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Date: 10/1/2014 9:51:00 AM
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Author: Lias, Courtney H
Date: 10/1/2014 9:51:00 AM
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Range: e.g.,

Author: Lias, Courtney H
Date: 10/1/2014 9:52:00 AM
Type: Delete
Range: has previously regulated instruments manufactured by a firm for in vitro diagnostic (IVD) testing as medical devices and not as LDTs

Author: Lias, Courtney H
Date: 10/1/2014 9:52:00 AM
Type: Insert
Range: has had extensive discussions with Theranos about this activity

Author: Lias, Courtney H
Date: 10/1/2014 9:52:00 AM
Type: Insert
Range: or premarket approval (depending on the test)

Author: Lias, Courtney H
Date: 10/1/2014 9:53:00 AM
Type: Delete
Range: . Since the firm believes that their TSPU device and reagents are LDTs and not medical devices, it is unclear if they are manufactured under the Quality System Regulations.

Author: Lias, Courtney H
Date: 10/1/2014 9:53:00 AM
Type: Insert
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Author: Lias, Courtney H
Date: 10/1/2014 9:53:00 AM
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Range: future

Author: Lias, Courtney H
Date: 10/1/2014 9:53:00 AM
Type: Insert
Range: (e.g., Walgreens pharmacies)

Author: Lias, Courtney H
Date: 10/1/2014 9:53:00 AM
Type: Delete
Range: where

Author: Lias, Courtney H
Date: 10/1/2014 9:53:00 AM
Type: Insert
Range: whether the on-site

Author: Lias, Courtney H
Date: 10/1/2014 9:53:00 AM
Type: Delete
Range: the

Author: Lias, Courtney H
Date: 10/1/2014 9:53:00 AM
Type: Insert
Range: already

Author: Lias, Courtney H
Date: 10/1/2014 9:54:00 AM
Type: Insert
Range: . FDA has also informed Theranos that tests performed using their reagents on the TPSU require clearance or approval prior to being marketed

Author: Lias, Courtney H
Date: 10/1/2014 9:54:00 AM
Type: Delete
Range: ,

Author: Lias, Courtney H
Date: 10/1/2014 9:54:00 AM
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Range: .

Author: Lias, Courtney H
Date: 10/1/2014 9:54:00 AM
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Author: Lias, Courtney H
Date: 10/1/2014 9:54:00 AM
Type: Delete
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Author: Lias, Courtney H
Date: 10/1/2014 9:54:00 AM
Type: Insert
Range: or PMAs

Author: Lias, Courtney H
Date: 10/1/2014 9:55:00 AM
Type: Insert
Range: despite multiple requests form the Center.

Author: Lias, Courtney H
Date: 10/1/2014 9:55:00 AM
Type: Delete
Range: 510(k)s

Author: Lias, Courtney H
Date: 10/1/2014 11:29:00 AM
Type: Insert
Range: or PMA approval

Author: Lias, Courtney H
Date: 10/1/2014 11:29:00 AM
Type: Delete
Range: 510(k)

Author: Lias, Courtney H
Date: 10/1/2014 11:29:00 AM
Type: Insert
Range: or approval

Author: Lias, Courtney H
Date: 10/1/2014 11:29:00 AM
Type: Delete

Range: 510(k)

Author: Lias, Courtney H
Date: 10/1/2014 11:29:00 AM
Type: Insert
Range: or approval

Author: Lias, Courtney H
Date: 10/1/2014 11:29:00 AM
Type: Insert
Range: or PMAs

Author: Lias, Courtney H
Date: 10/1/2014 11:30:00 AM
Type: Delete
Range: 510(k)

Author: Lias, Courtney H
Date: 10/1/2014 11:30:00 AM
Type: Delete
Range: because they claim to be an LDT provider, not a manufacturer subject to FDA regulations

Author: Lias, Courtney H
Date: 10/1/2014 11:32:00 AM
Type: Delete
Range: The validation tests should be completed using only the instructions provided in the device labeling.

Document properties

Title: Template 1 - CDRH "For Cause" Directed Inspection Assignment Template
Author: williamsju
Company: US FDA
Comments: Initial QSEB review assigned 125 145 to foreign template, but is used here for a template that covers domestic and foreign.
Attached Template: Normal.dotm
Page count: 1
Paragraph count: 145
Line count: 438
Word count: 2763
Character count (spaces excluded): 16158
Character count (spaces included): 19087

Hyperlinks
Total Hyperlinks: 1

Name: MDRPolicy@fda.hhs.gov
Address: mailto:MDRPolicy@fda.hhs.gov
Range: MDRPolicy@fda.hhs.gov
Text to display: MDRPolicy@fda.hhs.gov